

SEP 27 2004

(Modified)

Application No.: 10/700,909

Filing Date: 11/04/2003

Applicant: John R. Erbey II, et al.

Title: Methods and Therapeutic Combinations for the Treatment of Autoimmune Disorders

Certificate of Mailing under 37 CFR 1.8

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Commissioner for Patents
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Ann Marie Cannoni, Reg. No. 35,972

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Documents enclosed:

Certificate of Mailing PTO/SB/92 -1 Page

Information Disclosure Statement - 3 Pages

Form PTO 1449 - 16 Pages

390 References (for a total of 6 Boxes)

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JFW

PATENT CASE CV06093US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

John R. Erbey II, et al.

: Examiner: To Be Assigned

For:

Methods and Therapeutic Combinations

: Group Art Unit: 1614

for the Treatment of Autoimmune Disorders

: Date: September 24, 2004

Serial No.: 10/700,909

Filed: 11/04/2003
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the following be considered and made record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent

application. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) _____ filed _____, respectively.

(b) No fee is believed due because:

- ☐ This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- ☐ This Information Disclosure Statement is being concurrently filed with the above-identified application.
- ☐ This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- ☒ This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c) ☐ This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or

☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

(d) ☐ This Information Disclosure Statement is being filed on or before the payment of the issue fee; and

☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

Serial No. 10/700,909

September 24, 2004


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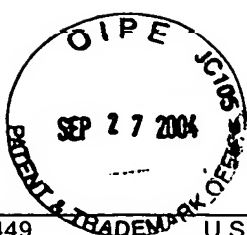
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 19-0395, Patent Case No. CV06093US01.

Respectfully submitted,
SCHERING-PLOUGH CORPORATION

Dated: **September 24, 2004**
SCHERING-PLOUGH CORPORATION
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530
Facsimile No.: (908) 298-5388

By:


Name: **Ann M. Cannoni**
Reg. No.: **35,972**
Attorney of Record
Telephone No.: (908) 298-5024



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:
CV6093US01

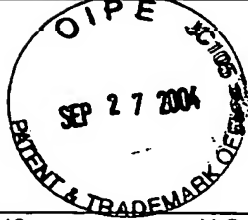
APPLICATION NO.:
10/700, 909
**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

APPLICANT:
John R. Erbey II, et al.
(Use several sheets if necessary)

FILING DATE:
11/04/2003

GROUP:
1614
FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATIO N	
							YES	N O
	AA	BE 884722 A	12/01/80	BELGIUM	C07D	AG1K	X(abs.)	
	AB	CA 2253769	11/29/99	CANADA	A61K	31/22		
	AC	DE 2046823 A	03/30/72	GERMANY	C07C		X(abs.)	
	AD	DE 2521113 A	03/18/76	GERMANY	C07C	87/34	X(abs.)	
	AE	EP 0002151 A1,B1	05/30/79	EUROPE	C07C	69/67		
	AF	EP 0010299 B1	02/15/84	EUROPE	A61K	45/06		
	AG	EP 0179559 A2	04/30/86	EUROPE	C07D	405/06		
	AH	EP 0199630 A1	10/29/86	EUROPE	C07D	205/08		
	AI	EP 0199630 B1	09/19/90	EUROPE	C07D	205/08		
	AJ	EP 0264231 A1	04/20/88	EUROPE	C07D	205/08		
	AK	EP 0266896 B1	05/11/88	EUROPE	C07D	471/04		
	AL	EP 0274873 B1	07/20/88	EUROPE	C07K	11/00		
	AM	EP 0288973 B1	11/02/88	EUROPE	C07D	417/06		
	AN	EP 0311366 B1	04/12/89	EUROPE	C07D	471/04		
	AO	EP 0333268 A1	09/20/89	EUROPE	C07F	7/18		
	AP	EP 0337549 A1	10/18/89	EUROPE	C07D	205/08		
	AQ	EP 0337549 B1	10/04/95	EUROPE	C07D	205/08		
	AR	EP 0365364 A2	04/25/90	EUROPE	C07D	205/08		
	AS	EP 0369686 A1	05/23/90	EUROPE	C07D	463/00		
	AT	EP 0375527 A1	06/27/90	EUROPE	C07D	205/08	X(abs.)	
	AU	EP 0401705 A3	12/12/90	EUROPE	A61K	31/66		
	AV	EP 0415487 A2	03/06/91	EUROPE	C07D	205/08		
	AW	EP 0455042 A1	11/06/91	EUROPE	A61K	31/19		
	AX	EP 0457514 A1	11/21/91	EUROPE	A61K	45/06		
	AY	EP 0457514 B1	08/21/96	EUROPE	A61K	45/06		
	AZ	EP 0461548 A3	12/18/91	EUROPE	A61K	31/365		
	BA	EP 0462667 A2	12/27/91	EUROPE	C07D	205/08		
	BB	EP 0475148 A1	03/18/92	EUROPE	A61K	31/215		
	BC	EP 0475755 B1	03/18/92	EUROPE	C07D	403/06		
	BD	EP 0481671 A1	04/22/92	EUROPE	C07D	205/08		
	BE	EP 0482498 A3	04/29/92	EUROPE	A61K	31/66		
	BF	EP 0524595 A1	01/27/93	EUROPE	C07D	205/08		
	BG	EP 0720599 B1	07/10/96	EUROPE	C07D	205/08		
	BH	EP 0793958 A2	09/10/97	EUROPE	A61K	9/16	X(abs)	
	BI	EP 0814080 A1	12/29/97	EUROPE	C07D	267/14		
	BJ	EP 0904781 A2	03/31/99	EUROPE	A61K	31/215		
	BK	EP 1048295 A2	11/02/00	EUROPE	A61K	31/216		
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	BO	GB 902658	08/09/62	GB	C07D			
	BP	GB 1415295	11/26/75	GB	C07C	59/26		



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:
CV06093US01

APPLICATION NO.:
10/700,909
**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

APPLICANT:
John R. Erbey II, et al.

FILING DATE:
11/04/2003

GROUP:
1614
(Use several sheets if necessary)
FOREIGN PATENT DOCUMENTS

	BQ	GB 2329334 A	03/24/99	GB	A61K	45/00		
	BR	JP 028057	10/01/81	JAPAN			X(abs.)	
	BS	JP 121479	12/10/86	JAPAN			X(abs.)	
	BT	JP 136485	05/26/81	JAPAN			X(abs.)	
	BU	JP 180212	03/24/86	JAPAN			X(abs.)	
	BV	JP 219681	04/14/87	JAPAN			X(abs.)	
	BW	JP 5194209 A	08/03/93	JAPAN	A61K	031/22	X(abs.)	
	BX	JP 5239020 A	1993	JAPAN	C07D	205/08	X(abs.)	
	BY	JP 4054182 A	1992	JAPAN	C12P	017/16	X(abs.)	
	BZ	JP 63017859 A	1988	JAPAN	C07D	205/08	X(abs.)	
	CA	JP 4266869 A	1992	JAPAN	C07D	205/08	X(abs.)	
	CB	JP 4356195 A	1993	JAPAN			X(abs.)	
	CC	JP 4356495	12/10/92	JAPAN			X(abs.)	
	CD	JP 5058993 A	1993	JAPAN			X(abs.)	
	CE	JP 61280295 A	1987	JAPAN			X(abs.)	
	CF	JP 95051558 B2	06/05/95	JAPAN	C07D	205/08	X(abs.)	
	CG	JP 91068020	10/25/91	JAPAN	C07D	205/08	X(abs.)	
	CH	JP 94047573	06/22/94	JAPAN	C07D	205/08	X(abs.)	
	CI	WO 82/01649	05/27/82	PCT	A61K	9/52	X(abs.)	
	CJ	WO 87/04429	07/30/87	PCT	C07D	205/08		
	CK	WO 88/04656	06/30/88	PCT	C07D	405/04		
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	CM	WO 91/03249	03/21/91	PCT	A61K	31/785	X(abs.)	
	CN	WO 92/13837	08/20/92	PCT	C07D	205/08		
	CO	WO 93/02048	02/04/93	PCT	C07D	205/08		
	CP	WO 93/07167	04/15/93	PCT	C07J	71/00		
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	CS	WO 94/14433	07/07/94	PCT	A61K	31/395		
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	CU	WO 94/20535	09/15/94	PCT	C07K	13/00		
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FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV06093US01		APPLICATION NO.: 10/700,909	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>				APPLICANT: John R. Erbey II, et al.			
				FILING DATE: 11/04/2003		GROUP: 1614	
FOREIGN PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
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	FH	WO 00/31548	06/02/00	PCT	G01N	33/68	
	FI	WO 00/32189	06/08/00	PCT	A61K	31/415	
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	GD	WO 00/57918	10/05/00	PCT	A61K	47/44	
	GE	WO 00/60107	10/12/00	PCT	C12P	17/10	
	GF	WO 00/63153	10/26/00	PCT	C07C	69/734	
	GG	WO 00/63161	10/26/00	PCT	C07C	237/30	

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				FILING DATE: 11/04/2003		GROUP: 1614	
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	GH	WO 00/63190	10/26/00	PCT	C07D	265/38	
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	GJ	WO 00/63209	10/26/00	PCT	C07D	471/04	
	GK	WO 00/63703	10/26/00	PCT	G01N	33/92	
	GL	WO 00/69412	11/23/00	PCT	A61K	9/127	
	GM	WO 00/69445	11/23/00	PCT	A61K	31/785	
	GN	WO 00/72825	12/7/00	PCT	A61K	9/14	
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	GV	WO 01/00603	01/04/01	PCT	C07D	277/24	
	G W	WO 01/08686	02/08/01	PCT	A61K	31/495	
	GX	WO 01/12176	02/22/01	PCT	A61K	31/16	
	GY	WO 01/12187	02/22/01	PCT	A61K	31/404	
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	HB	WO 01/14350	03/01/01	PCT	C07D	277/34	X(abs.)
	HC	WO 01/14351	03/01/01	PCT	C07D	277/34	X(abs.)
	HD	WO 01/15744	03/08/01	PCT	A61K	49/00	
	HE	WO 01/16120	03/08/01	PCT	C07D	263/32	
	HF	WO 01/17994	03/15/01	PCT	C07D	413/12	
	HG	WO 01/18210	03/15/01	PCT	C12N	15/12	
	HH	WO 01/21181	03/29/01	PCT	A61K	31/675	X(abs.)
	HI	WO 01/21259	03/29/01	PCT	A61P		
	HJ	WO 01/21578	03/29/01	PCT	C07C	235/60	X(abs.)
	HK	WO 01/21647	03/29/01	PCT	C07K	14/00	
	HL	WO 01/22962	04/05/01	PCT	A61K	31/435	
	HM	WO 01/25225	04/12/01	PCT	C07D	317/18	
	HN	WO 01/25226	04/12/01	PCT	C07D	327/04	
	HO	WO 01/30343	05/03/01	PCT	A61K	31/40	
	HP	WO 01/32161	05/10/01	PCT	A61K	31/00	
	HQ	WO 01/35970	05/25/01	PCT	A61K	35/76	
	HR	WO 01/40192	06/07/01	PCT	C07D	217/26	X(abs.)

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FOREIGN PATENT DOCUMENTS							
	HS	WO 01/45676	06/28/01	PCT	A61K	9/24	
	HT	WO 01/49267	07/12/01	PCT	A61K	9/14	
	HU	WO 01/64221	09/07/01	PCT	A61K	31/52	
	HV	WO 01/76632	10/18/01	PCT	A61K	45/06	
	HW	WO 02/50090	06/27/02	PCT	C07H	15/26	
	HX	WO 02/058696	08/01/02	PCT	A61K	31/397	
	HY	WO 02/058731	08/01/02	PCT	A61K	45/06	
	HZ	WO 02/058732	08/01/02	PCT	A61K	45/06	
	IA	WO 02/058733	08/01/02	PCT	A61K	45/06	
	IB	WO 02/058734	08/01/02	PCT	A61K	45/06	
	IC	WO 02/058685	08/01/02	PCT	A61K	31/00	
	ID	WO 02/064130	08/22/02	PCT	A61K	31/195	
	IE	WO 02/064549	08/22/02	PCT	C07C	275/34	
	IF	WO 02/064664	08/22/02	PCT	C08G	77/02	
	IG	WO 02/072104	09/19/02	PCT	A61K	31/54	
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	II	WO 02/26729	04/04/02	PCT	C07D	311/66	
	IJ	WO 02/064094	08/22/02	PCT	A61K		
	IK	WO 02/50027	06/27/02	PCT			
	IL	WO 02/50060	06/27/02	PCT			
	IM	WO 02/50068	06/27/02	PCT			
	IN	WO 94/26738	11/24/94	PCT			
	IO	EP 1 036 563 A1	09/20/00	EPO			
	IP	EP 0 753 298 A1	01/15/97	EPO			
	IQ	WO 01/34148	05/17/01	PCT			
	IR	WO 01/60807	08/23/01	PCT			
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	IT	WO 03/039542	05/15/03	PCT			
	IU	WO 03/074101	09/12/03	PCT			
	IV	WO 03/088962	10/30/03	PCT			
	IW	WO 03/018024	03/06/03	PCT	A61K	31/55	
	IX	WO 03/018059	03/06/03	PCT	A61K	45/06	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	IY	Exhibit A: SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary			
	IZ	Exhibit B: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JA	Exhibit C: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JB	Exhibit D: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JC	Exhibit E: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JD	Exhibit F: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JE	Exhibit G: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JF	Exhibit H: SCH 58235 (ezetimibe), Drug Formulation Development Summary			
	JG	Exhibit 1: Master Sheet for the SCH 58235 and Lovastatin Research Study, <i>Schering-Plough Research Institute</i> (Protocol No. C906-411), page 1576-1585			
	JH	Exhibit 2: Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, <i>Peninsular Testing Corporation</i> , page 106-112			
	JI	Exhibit 3: Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," <i>Schering-Plough Research Institute</i> (Protocol No. C98-010), page 1558-1566			
	JJ	Exhibit 4: Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent, <i>Peninsular Testing Corporation</i> , page 124-130			
	JK	Exhibit 5: Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," <i>Schering-Plough Research Institute</i> , page 1-8			
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	JQ	T. Durst <i>et al</i> , "Metallation of N-Substituted β -Lactams. A Method of the Introduction of 3-substituents into β -Lactams" <i>Canadian Journal of Chemistry</i> , 50:3196-3201 (1971)			
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	JW	Panfil, I. <i>et al.</i> "Synthesis of β -Lactams from α , β -Unsaturated Sugar δ -Lactones" 24 <i>Heterocycles</i> 6 :1609-1617 (1986)		
	JX	D. Roger Illingworth, "An Overview of Lipid-Lower Drugs" <i>Drugs</i> 36 :63:71 (1988)		
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EXAMINER			DATE CONSIDERED		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

Applicant: John R. Erbey II, et al.
 Serial No.: 10/700,909 Atty.: AMC:sa
 Filed: 11/04/2003 Case No.: CV06093US01
 For: Methods and Therapeutic Combinations...

Enclosed:

- ☒ Certificate of Mailing PTO/SB/92 (1 page)
- ☐ Response Transmittal Form (PTO/SB/21)
- ☐ Fee Transmittal (PTO/SB/17) In Duplicate
- ☐ Response To Notice to File Missing Parts (____pages)
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- ☐ Declaration/Power of Attorney (Exec./Unexec./Copy) (____pages)
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- ☐ Sequence Listing Statement (____pages)
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